

### **Amendments to the Drawings:**

Because FIG. 7 that was submitted with the AMENDMENT AND RESPONSE filed December 13, 2004 was deemed to include new matter, Applicants are adopting the suggestion of the Examiner to not request entry of the amended drawings and the references to these drawings in the amended specification. Accordingly, in accordance with the Examiner's suggestion, it is requested that the new matter introduced by the drawings submitted with the AMENDMENT AND RESPONSE filed December 13, 2004 not be entered. It is also requested that those portions of the specification introduced to describe the aforementioned drawings not be entered. See **Amendment to the Specification** on pages 3-5 of this AMENDMENT AND RESPONSE UNDER 37 C.F.R. 1.116.

## **REMARKS**

Claims 1, 3-16, and 18-28 remain in the application. Claims 1, 3, 4, 16, 18, and 19 have been amended. Claims 2 and 17 have been cancelled. The specification has been amended. The new drawings FIGS. 2A, 2B, 7, and 8 previously presented in the AMENDMENT AND RESPONSE filed December 13, 2004 are withdrawn. FIG. 9 has been given its original figure number as FIG. 7. Reconsideration of this application, as amended, is respectfully requested.

Claims 1 and 16 have been amended to specify that the at least one reagent comprises at least one enzyme and at least one mediator, the at least one enzyme being reactive with the at least one mediator. Support for this amendment can be found at page 4, line 34 through page 5, line 15 of the specification, at page 16, line 30 through page 17, line 3 of the specification, and in Table 1 of the specification.

Claims 2 and 17 have been canceled. Claims 3 and 18 have been amended to conform to the terminology of claims 1 and 16, respectively. Claims 4 and 19 have been amended to conform to the terminology of claims 1 and 16, respectively.

The specification has been amended to delete reference the amended drawings presented in the AMENDMENT AND RESPONSE filed December 13, 2004, and the references to these drawings presented in the AMENDMENT AND RESPONSE filed December 13, 2004 at the suggestion of the Examiner, which can be found at page 21 of the Final Rejection.

Because the foregoing amendment touches the merits of the application, a showing under 37 C.F.R. 1.116(c) is expected. The amendment is necessary to overcome the rejections based on the newly cited reference Gilmartin, U. S. Patent No. 5,795,453. The amendment was not earlier presented because Applicants were unaware of the Gilmartin reference and because Gilmartin was cited for the first time by the Examiner in the Final Rejection. The present amendment is being presented at this time because the claims, if amended as proposed, would avoid the rejections based on 35 U.S.C. § 102 and 35 U.S.C. § 103, and thus the amendment would place the case in condition for allowance or in better condition for appeal. The claims, if

amended as proposed, would avoid the rejections on the references. In view of the foregoing reasons, the Examiner has sufficient grounds for entering the amendment.

Claims 5 and 20 stand rejected under 35 U. S. C. § 112, first paragraph, as failing to comply with the enablement requirement. This rejection is respectfully traversed for the following reasons.

These claims are supported at page 16, lines 12-16 of the specification, where it is stated:

.....The elongated portions of the conductive tracks 14a, 14b, 14a', 14b' can optionally be overlaid with a track of conductive material, preferably made of a mixture comprising silver particles and silver chloride particles. This optional overlying track results in lower resistance, and consequently, higher conductivity.....

These optional embodiments are fully described and simple to visualize. Accordingly this ground of rejection should be withdrawn.

Claims 1-5, 8, and 10 were rejected under 35 U. S. C. § 102 (b) as being anticipated by U. S. Patent No. 5,795,453 to Gilmartin. This rejection is respectfully traversed for the following reasons.

Gilmartin, U. S. Patent No. 5,795,453 (hereinafter "Gilmartin"), discloses electrode assemblies and methods in which electron transfer between a redox reaction product and an electrically conductive electrode material is facilitated by a metallo macrocyclic compound, preferably a metallo isoindole ringed compound and more preferably a ferro isoindole ringed compound. The redox reaction is usually catalyzed by a redox enzyme such as an oxidase. FIG. 1 of Gilmartin shows a screen printed electrode assembly arrangement and geometry that can be used measure multiple analytes simultaneously. Connecting strip A can be inserted into a spade connector to a potentiostat during operation. An insulation strip B can be provided for by means of a 3 mm wide strip of tape or preferably an insulating layer. The working area C can be used as a detection zone. D depicts an

inert solid support, such as PVC (polyvinyl chloride), for a screen printed electrode.

Claims 1 and 16 have been amended to specify that at least one reagent is incorporated in at least one of the first conductive track leading from the working electrode to the electrical contact associated with the working electrode, or the electrical contact associated with the working electrode, the at least one reagent comprising at least one enzyme and at least one mediator, the at least one enzyme being reactive with the at least one mediator. Thus, the claims of the present application describe a biosensor where at least one of the first conductive track leading from the working electrode to the electrical contact associated with the working electrode or the electrical contact associated with the working electrode contains at least one enzyme that is reactive with at least one mediator. In the claims of the present application, the mediator reacts with the enzyme, thereby resulting in a measurable current. For further discussion relating to the reactivity between the at least one enzyme and the at least one mediator, **see page 16, line 30 through page 17, line 3 of the specification and page 23, lines 1-21 of the specification.**

Gilmartin discloses an electrochemical sensor for the measurement of an analyte. The sensor uses an oxidase. The compound that is incorporated in the electrode, i.e., metallo macrocyclic compound, does not react with the enzyme. The compound, i.e., metallo macrocyclic compound, reacts with hydrogen peroxide, which is produced when the enzyme reacts with the analyte. Hydrogen peroxide diffuses to the metallo macrocyclic compound and then becomes oxidized. FIG. 2 of Gilmartin shows that even though the oxidase enzyme (E) reacts with a substrate (S), the reaction product of the reaction between the enzyme and the substrate, i.e.,  $H_2O_2$ , reacts with the FePC mediator at the electrode-solution interface. The claims of the present application are patentably distinguishable from the arrangement shown in FIG. 2 of Gilmartin, because the enzyme recited in the claims of the present application reacts directly with the mediator recited in the claims of the present application. In the arrangement shown in Gilmartin, the enzyme does not react with the mediator. For this reason, Gilmartin does not anticipate any of the claims of the present application.

Claims 1-28 were rejected under 35 U. S. C. 103(a) as being unpatentable over Feldman in view of Gilmartin. This rejection is respectfully traversed for the following reasons.

Feldman et al., U. S. Patent No. 6, 299,757 (hereinafter "Feldman et al."), was described on page 15 of the AMENDMENT AND RESPONSE filed December 13, 2004.

Feldman et al. does not disclose or suggest that at least one reagent is incorporated in at least one of the first conductive track leading from the working electrode to the electrical contact associated with the working electrode or the electrical contact associated with the working electrode. In Feldman et al., the reagents are deposited over the electrodes only. Claims 1 and 16 have been amended to specify that at least one reagent is incorporated in at least one of the first conductive track leading from the working electrode to the electrical contact associated with the working electrode, or the electrical contact associated with the working electrode, the at least one reagent comprising at least one enzyme and at least one mediator, the at least one enzyme being reactive with the at least one mediator. Thus, the claims of the present application describe a biosensor where at least one of the first conductive track leading from the working electrode to the electrical contact associated with the working electrode or the electrical contact associated with the working electrode contains at least one enzyme that is reactive with at least one mediator. In the claims of the present application, the mediator reacts with the enzyme, thereby resulting in a measurable current.

As stated previously, Gilmartin discloses an electrochemical sensor for the measurement of an analyte. The sensor uses an oxidase. The compound that is incorporated in the electrode, i.e., metallo macrocyclic compound, does not react with the enzyme. The compound, i.e., metallo macrocyclic compound, reacts with hydrogen peroxide, which is produced when the enzyme reacts with the analyte. Hydrogen peroxide diffuses to the metallo macrocyclic compound and then becomes oxidized. FIG. 2 of Gilmartin shows that even though the oxidase enzyme (E) reacts with a substrate (S), the reaction product of the reaction between the enzyme and the substrate, i.e.,  $H_2O_2$ , reacts with the FePC mediator at the electrode-

solution interface. The claims of the present application are patentably distinguishable from the arrangement shown in FIG. 2 of Gilmartin, because the enzyme recited in the claims of the present application reacts directly with the mediator recited in the claims of the present application. In the arrangement shown in Gilmartin, the enzyme does not react with the mediator. Thus, Gilmartin teaches away from the invention recited in the claims of the present application. Accordingly, the combination of Feldman et al. and Gilmartin teaches away from the present invention. In effect, the rejection is based on a piecemeal reconstruction of the prior art, which is impermissible, because it is impermissible within the framework of 35 U. S. C. § 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. Therefore, the combination of Feldman et al. and Gilmartin fails to render claims 1 and 16 obvious to one ordinary skill in the art. Claims 3-15 depend either directly or indirectly from claim 1. Claims 18-28 depend either directly or indirectly from claim 16. Accordingly, this ground of rejection should be withdrawn.

Claims 1 - 4, 10, 12, 13, and 15 stand rejected under 35 U. S. C. § 102 (b) as being anticipated by U. S. Patent No. 6,129,823 to Hughes et al. This rejection is respectfully traversed for the following reasons.

Although the rejection is based on Hughes et al. alone, the reason relies on the combination of Hughes et al. and Gilmartin. Accordingly, the response to the rejection will be based on the combination of Hughes et al. and Gilmartin.

Hughes et al., U. S. Patent No. 6,129,823 (hereinafter "Hughes et al."), was described on page 15 of the AMENDMENT AND RESPONSE filed December 13, 2004.

Hughes et al. et al. does not disclose or suggest that at least one reagent is incorporated in at least one of the first conductive track leading from the working electrode to the electrical contact associated with the working electrode or the electrical contact associated with the working electrode. In Hughes et al., the reagents are deposited over the electrodes only. Claim 1 has been amended to specify that at least one reagent is

incorporated in at least one of the first conductive track leading from the working electrode to the electrical contact associated with the working electrode, or the electrical contact associated with the working electrode, the at least one reagent comprising at least one enzyme and at least one mediator, the at least one enzyme being reactive with the at least one mediator. Thus, the claims of the present application describe a biosensor where at least one of the first conductive track leading from the working electrode to the electrical contact associated with the working electrode or the electrical contact associated with the working electrode contains at least one enzyme that is reactive with at least one mediator. In the claims of the present application, the mediator reacts with the enzyme, thereby resulting in a measurable current.

As stated previously, Gilmartin discloses an electrochemical sensor for the measurement of an analyte. The sensor uses an oxidase. The compound that is incorporated in the electrode, i.e., metallo macrocyclic compound, does not react with the enzyme. The compound, i.e., metallo macrocyclic compound, reacts with hydrogen peroxide, which is produced when the enzyme reacts with the analyte. Hydrogen peroxide diffuses to the metallo macrocyclic compound and then becomes oxidized. FIG. 2 of Gilmartin shows that even though the oxidase enzyme (E) reacts with a substrate (S), the reaction product of the reaction between the enzyme and the substrate, i.e.,  $H_2O_2$ , reacts with the FePC mediator at the electrode-solution interface. The claims of the present application are patentably distinguishable from the arrangement shown in FIG. 2 of Gilmartin, because the enzyme recited in the claims of the present application reacts directly with the mediator recited in the claims of the present application. In the arrangement shown in Gilmartin, the enzyme does not react with the mediator. Thus, Gilmartin teaches away from the invention recited in the claims of the present application. Accordingly, the combination of Hughes et al. and Gilmartin teaches away from the present invention. In effect, the rejection is based on a piecemeal reconstruction of the prior art, which is impermissible, because it is impermissible within the framework of 35 U. S. C. § 103 to pick and choose. Therefore, the combination of Hughes et al. and Gilmartin fails to render claim 1 obvious to one ordinary skill in the art. Claims

3, 4, 10, 12, 13, and 15 depend either directly or indirectly from claim 1.  
Accordingly, this ground of rejection should be withdrawn.

In view of the foregoing, it is submitted that claims 1, 3-16, and 17-28,  
as amended, are in condition for allowance, and official Notice of Allowance is  
respectfully requested.

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A handwritten signature in cursive script, reading "David L. Weinstein", written over a horizontal line.

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